CLAIMS

What is claimed is:

1. A testosterone oral dosage formulation for administration to a subject comprising:

a substantially solid polyethylene glycol carrier which comprises from about 30% w/w to about 80% w/w of the formulation, having a molecular weight range of from about 100 to about 20,000 or a mixture thereof; and

a therapeutically effective amount of testosterone, or is pharmaceutically acceptable salts or esters, or a mixture thereof in the carrier ranging from about 2.5 mg to about 45 mg, said formulation providing a therapeutically effective testosterone serum level ranging from about 15 ng/dl to about 1200 ng/dl when administered to the subject.

2. The formulation of claim 1, wherein the amount of testosterone in the carrier is from about 5mg to about 15 mg.

3. The formulation of claim 2, wherein the amount of testosterone is about 10mg.

4. The formulation of claim 1, wherein the polyethylene glycol of said carrier has an average molecular weight of from about 400 to about 15,000.

5. The formulation of claim 4, wherein the polyethylene glycol of said carrier has an average molecular weight of from about 1,000 to about 10,000.

6. The formulation of claim 1, wherein the carrier comprises from about 50% w/w to about 80% w/w of the formulation.

7. The formulation of claim 6, wherein the carrier comprises from about 60% w/w to about 80% w/w of the formulation.

8. The formulation of claim 7, wherein the carrier comprises about 70% w/w of the formulation.

10. A testosterone oral dosage formulation for administration to a subject, comprising:

a substantially solid polyethylene glycol carrier having a molecular weight of from about 1,000 to about 10,000, said carrier comprising at least about 70% w/w of the formulation; and

from about 10 mg to about 15 mg of testosterone in the carrier.

11. A method of administering testosterone to a subject, comprising:

providing a testosterone formulation as recited in any one of Claims 1-10; and

orally administering the formulation to the subject.

12. The method of claim 11, wherein the subject is a male.

13. The method of claim 11, wherein the subject is a female.

14. A method of treating or ameliorating a condition in a subject for which testosterone is effective comprising:

providing a testosterone formulation as recited in any one of Claims 1-10; and

orally administering the formulation to the subject in a therapeutically effective regimen.

15. A method of making an oral dosage testosterone formulation, comprising:

forming a dispersion of testosterone in a molten polyethylene glycol carrier;

cooling the dispersion into a substantially solid mass; and

dividing the mass into portions suitable for administration of a single testosterone dose.

16. The method of claim 15, further comprising extruding the molten polyethylene glycol carrier during the step of cooling to form an extrusion product.

17. The method of claim 16, further comprising cutting the extrusion product into caplets.

18. The method of claim 15, wherein the step of dividing further comprises reducing the solid mass to flakes, granules, or powder and separating the flakes granules, or powder into a single dosage amount.

19. The method of claim 18, further comprising molding the single dosage unit into a solid state form.

20. The method of claim 19, wherein the step of molding is accomplished by injection molding.

21. The method of claim 19, wherein the step of molding is accomplished by pressing.

22. The method of claim 19, wherein the solid state form is a tablet.

23. The method of claim 18, further comprising encapsulating the single dosage amount with a capsule.

24. The method of claim 15, wherein the testosterone is uniformly dispersed in the molten polyethylene glycol carrier.